DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

Advisory Committee: Change of Name and Function; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name and function of the Drug Abuse Advisory Committee. This action is being taken to reflect changes made to the charter for this advisory committee.

DATES: This rule is effective July 11, 2002.

FOR FURTHER INFORMATION CONTACT: Theresa Green, Committee Management Officer (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Drug Abuse Advisory Committee, which was established on May 31, 1978, has been changed. The agency decided that the name ''Drug Safety and Risk Management Advisory Committee'' would more accurately describe the subject areas for which the committee is responsible. The mandate of the committee is being expanded to include drug specific risk management and medication errors, educational campaigns and risk communication messages, and advice on potential drug name changes to reduce potential medication errors. The committee reviews and evaluates data on risk management plans, provides active surveillance methodologies, trademark studies, methodologies for risk management communication, and related issues.

The Drug Abuse Advisory Committee name was changed and its functions expanded in the charter renewal dated May 31, 2002. FDA is revising 21 CFR 14.100(c)(7) to reflect these changes.

Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(B) and (d) and 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public procedure and to proceed to an immediately effective regulation. Such notice and procedures are unnecessary and are not in the public interest, because the final rule is merely codifying the new name and expanded function of the advisory committee reflect the current committee charter.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. Section 14.100 is amended by revising the heading of paragraph (c)(7) and paragraph (c)(7)(ii) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(7) *Drug Safety and Risk Management Advisory Committee*.

* * * * *

(ii) Function: Reviews and evaluates data on risk management plans, provides active surveillance methodologies, trademark studies, methodologies for risk management communication, and related issues.

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Dated: July 5, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–17401 Filed 7–10–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's address for BioScience Division of Milk Specialties Co.

DATES: This rule is effective July 11, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: BioScience Division of Milk Specialties Co., Illinois and Water Sts., P.O. Box 278, Dundee, IL 60118, has informed FDA of a change of sponsor's address to 1902 Tennyson Lane, Madison, WI 53704. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for ''BioScience Division of Milk Specialties Co.'' and in the table in paragraph (c)(2) by revising the entry for ''032761'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
BioScience Division of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704	032761
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
032761	BioScience Division of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704
* * * * * * *	

Dated: May 28, 2002.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 02–17405 Filed 7–10–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Hydrochloride

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pharmacia and Upjohn Co. The supplemental NADA provides for injection of ceftiofur hydrochloride suspension in cattle for the treatment of acute metritis.

DATES: This rule is effective July 11, 2002.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7572, e-mail: cburnste@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed a supplemental application to NADA 140–890 that provides for use of EXCENEL (ceftiofur hydrochloride) RTU Sterile Suspension by intramuscular or subcutaneous injection in cattle for the treatment of acute metritis (0 to 14 days post partum) associated with bacterial organisms susceptible to ceftiofur. The supplemental NADA is approved as of February 8, 2002, and the regulations are amended in § 522.314 (21 CFR 522.314) to reflect the approval. The basis of approval is discussed in the freedom of information summary. Section 522.314 is also being revised to reflect a current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental application approval qualifies for 3 years of marketing exclusivity beginning February 8, 2002, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplemental application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(5) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.314 is amended by revising the section heading, and paragraphs (a), (d)(1)(i), (d)(1)(iii), and (d)(2) to read as follows:

§ 522.314 Ceftiofur hydrochloride.

(a) *Specifications.* Each milliliter of suspension contains ceftiofur hydrochloride equivalent to 50 milligrams (mg) of ceftiofur.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* 3 to 5 mg per kilogram (/kg) of body weight by intramuscular injection. Treatment should be repeated at 24-hour intervals for a total of 3 consecutive days.

* * * * *

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Dosage.* 1.1 to 2.2 mg/kg of body weight by intramuscular or subcutaneous injection, at 24-hour intervals for 3 to 5 consecutive days. For bovine respiratory disease, 2.2 mg/kg of body weight may be administered twice at a 48-hour interval. For acute metritis, administer 2.2 mg/kg of body weight daily for 5 consecutive days.

(ii) *Indications for use.* For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia* spp. (*Pasteurella haemolytica*), *P. multocida*, and *Haemophilus somnus*; acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with